NOV - 8 2005

CAPINTEC, INC.

September 7, 2005

K052595

RE: Summary of Safety and Effectiveness Information for the Capintec CRC 15Ultra.

The Capintec CRC 15Ultra is a multiple detector system, which may include up to eight sealed pressurized re-entrant well chambers, plus a high energy beta counter, and a well counter. The CRC 15Ultra combines the features of several well established Capintec models: CRC 35R, CRC 15R, Beta Counter, and Caprac R Counter into one unit with flexible configurations which are field upgradeable. The 15Ultra incorporates enhanced electronic circuitry and faster microprocessor capabilities, which extends it capability to network eight ionization chambers, as did the CRC 35R. However, the CRC 15Ultra can also add the detector assembly from the Beta C Counter, or the detector assembly from the Caprac R Well Counter, to the same universal readout. The basic design concepts, functionality, calculations, algorithms, and response are the same. The 15Ultra is a far more cost effective solution to a user who requires multiple chambers and detectors when compared to the cost of purchasing three separate units.

The predicate devices, upon which the CRC15Ultra is based, have a long history of safe and effective use in the field. The unit is intended for use by trained nuclear medicine technologists, nuclear medicine physicians, or medical phyicists in clinical applications.

The CRC 15Ultra has also been tested and approved to the following safety standards for laboratory equipment:

IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1 General Requirements
IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 2 Particular Requirement for In Vitro Diagnostic Equipment
IEC 61326 Electrical equipment for electrical equipment for measurement, control, and laboratory use-EMC requirements
UL 61010A-1 Electrical Equipment for Laboratory Use; Part 1: General Requirements
CAN/CSA-C22.2 No. 61010-1:2004 Standard for Safety Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
CAN/CSA-C22.2 No. 61010-2-101-04 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-101: Particular Requirements for In Vitro Diagnostics (IVD) Medical Equipment

540 Alpha Drive • Pittsburgh, PA 15238 U.S.A. • (412) 963-1988 FAX (412) 963-0610

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2005

Ms. Mary Ann Dell
Vice President & General Manager
CAPINTEC, INC.
540 Alpha Drive
PITTSBURGH PA 15238

Re.: K052595
Trade/Device Name: CRC 15ULTRA Dose Calibrator
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: KPT

Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: JAQ
Dated: September 6, 2005
Received: September 21, 2005

Dear Ms. Dell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registrations, listing of devices, good manufacturing practice, labeling and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advices that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of he Act or any Federal statues and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix # 2

Indications for Use Form-

Page _____ of _____

510(k) Number K052595

Device Name: CRC 15Ultra

Indications For Use: The CRC 15Ultra multiple chamber dose calibrator, which includes optional beta counter and well counter, is intended to be used by qualified nuclear medicine technologists to measure a wide range radiopharmaceuticals, including high energy beta and gamma emitters. It is also designed for use by trained medical physicists to measure the output of most radioactive brachytherapy sources, including HDR, LDR and IVBT sources. All brachytherapy sources must be measured in the appropriate source holder. The well counter is designed for measurement of low activity radioactive sources or solutions, including laboratory test applications. This device is used in numerous research applications for measurement of radioactive materials.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052595